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(we will no longer accept paper/disc submissions)

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- Key words
- Manuscript files in Word, WordPerfect, or Text formats
- Figures/Images in TIF, EPS, PDF, or JPG formats
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Kind of figure/File model/Ideal resolution/ Minimum resolution

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For detailed instructions regarding style and layout refer to "Uniform requirements for manuscripts submitted to biomedical journals". Copies of this document may be obtained on the website <http://www.icmje.org>. Articles should be submitted under conventional headings of introduction, methods and materials, results, discussion, but other headings will be considered if more suitable. For Uniform Requirements for Sample References go to http://www.nlm.nih.gov/bsd/uniform_requirements.html.

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A cover letter is required and must state that the manuscript: has not been published elsewhere, except in abstract form is not under simultaneous consideration by another journal. Once a decision is made by the Editor on your manuscript, the Journal office will send you an Author Release form and a Conflict of Interest form if your manuscript has been accepted for revision.

Abstracts

Original Articles and Case Reports should be accompanied by an abstract of 250 words or less on a separate page, in either English or French. The Journal will provide translation to the other language if required. Abstracts should consist of four paragraphs headed: Background (or Objective), Methods, Results and Conclusions.

Acknowledgements

Acknowledgements, including recognition of financial support, should be typed on a separate page at the end of the text. The SI system (système international d'unités) should be used in reporting all laboratory data, even if originally reported in another system. Temperatures are reported in degrees celsius. English language text may use either British or American spelling, but should be consistent throughout.

References

References should be numbered in the order of their citation in the text. Those cited only in tables and legends for illustrations are numbered according to the sequence established by the first identification in the text of a particular table or illustration.

Titles of journals should be abbreviated according to the style used in Index Medicus. References should list the names of up to six authors; if there are more, cite the first SIX, then et al.

Provide the full title, year of publication, volume number and inclusive pagination for journal articles. Do not reference unpublished or "submitted" papers; these can be mentioned in the body of the text and authors must provide five copies of "submitted" manuscripts.

Avoid "personal communications" and, if necessary, include them in the body of the text, not among the references. Reference citations should not include unpublished presentations or other non-accessible material. Books or chapter references should also include the place of publication and the name of the publisher.

For Reference Guidelines

www.nlm.nih.gov/bsd/uniform_requirements.html

Examples of correct forms of reference:

Journals

Rose ME, Huerbin MB, Melick J, Marion DW, Palmer AM, Schiding JK, et al. Regulation of interstitial excitatory amino acid concentrations after cortical contusion injury. *Brain Res.* 2002;935(1-2):40-6.

Chapter in a book

Meltzer PS, Kallioniemi A, Trent JM. Chromosome alterations in human solid tumors. In: Vogelstein B, Kinzler KW, editors. *The genetic basis of human cancer*. New York: McGraw-Hill; 2002. p. 93-113.

Tables

Type tables double-spaced on pages separate from the text. Provide a table number and title for each. Particular care should be taken in the preparation of tables to ensure that the data are presented clearly and concisely. Each column should have a short or abbreviated heading. Place explanatory matter in footnotes, not in the heading. Do not submit tables as photographs.

Review Articles

Review articles on selected topics are also published. They are usually invited, but unsolicited reviews will be considered. Review articles should be accompanied by an abstract of 150 words or less.

Brief Correspondence (formerly Peer Reviewed Letters)

Brief Correspondence articles to the Editor are published on various topics. The articles should be limited to approximately six double-spaced manuscript pages (2-3 Journal pages) and may include illustrations and tables.

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Correspondence to the Editor concerning matters arising in recent articles are welcome. Correspondence should be limited to two double-spaced pages and may include one illustration and a maximum of four references.

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Neuroimaging highlights are selected by the editor-in-chief and neuroimaging highlight editors on the basis of two factors. The first is high quality "state of the art" imaging of a novel and uncommon (or common with an uncommon twist) neurological or neurosurgical disorder. The second factor is the clinical novelty of the case.

Neuroimaging highlights require a figure of several panels that clearly outlines all features of the relevant imaging. For example, for MR images this may require different cuts and sequences, etc. Combining more than one imaging modality strengthens the report. The report may also benefit from a single additional panel in a figure if it is directly relevant, e.g. a pathological image or patient image. The text should include a very brief discussion of the case history confined to the relevant history, pertinent abnormal findings, and clinical course with outcome. An additional one to two paragraphs should briefly describe the neuroimaging panels present, and very briefly review relevant aspects of the literature. Overall, the neuroimaging highlights should be 500 words or less, with no more than 10 references.

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Suitability for publication is judged by the neuroimaging highlight editors, the editor-in-chief and up to one additional external referee.

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Neuroimaging highlights are selected by the editor-in-chief and neuroimaging highlight editors on the

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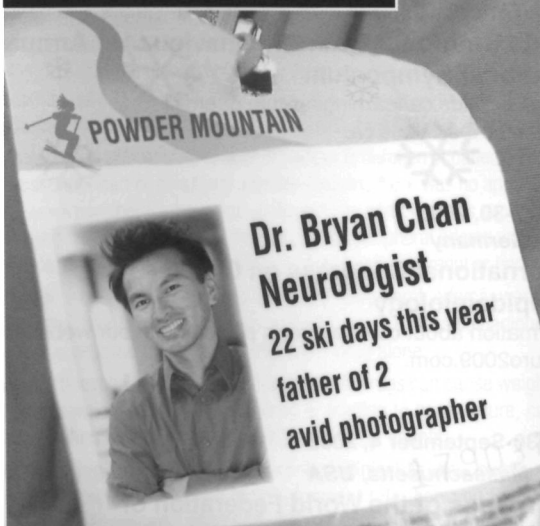
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CALENDAR OF EVENTS

February 16-17, 2009

Tel Aviv, Israel

5th Annual Update Symposium on Clinical Neurology and Neurophysiology

For more information, please visit our website at:
www.neurophysiology-symposium.com

March 11-14, 2009

Victoria, British Columbia, Canada

3rd International Conference on Fetal Alcohol Spectrum Disorder Integrating Research, Policy and Promising Practice Around the World: A Catalyst for Change

Register before the Early Bird Deadline of January 12, 2009 to take advantage of the reduced rate. Telephone (604) 822-7524 or Toll-free within BC: 1-877-328-7744; Fax: (604) 822-4835 OR Via E-Mail: jpad@interchange.ubc.ca or go to our website at www.peopleware.net/index.cfm?siteCode=1268.

March 11-15, 2009

Prague, Czech Republic

9th International Conference - Alzheimer's & Parkinson's Diseases: Advances, Concepts & New Challenges

For more information or to register, please visit
www.kenes.com/adpd

March 27-31, 2009

Marseille, France

Marseille Neurosurgery 2009 Joint Annual Meeting (EANS-SFNC)

For information, please visit our website at:
www.kenes.com/eans-sfnc

April 2-4, 2009

Washington, DC, USA

2nd International Conference on Psychogenic Movement Disorders and Other Conversion Disorders

For more information, please visit our website at:
www.movementdisorders.org/education/pmd

April 15-18, 2009

Rotterdam, The Netherlands

9th European Skull Base Society Meeting

For more information, please visit our website at:
www.esbs2009.eu

April 25-28, 2009

Rome, Italy

XI International Facial Nerve Symposium

For more information go to www.facialnerve2009.org.

April 25 - May 2, 2009

Seattle, Washington, USA

AAN Annual Meeting

For information go to: www.aan.com

May 7-9, 2009

Vancouver, British Columbia, Canada

International Vocational Outcomes in Traumatic Brain Injury Conference 2009

For information go to: www.tbicvancouver.com

May 10-13, 2009

Ottawa, Ontario, Canada

2nd Annual Canadian Network for Innovation in Education (CNIE) International Conference 2009

For more information please visit the 2009 International Conference website at www.learningconference.ca.

June 9-12, 2009

Halifax, Nova Scotia, Canada

44th Annual Congress of the Canadian Neurological Sciences Federation

For more information go to: www.cnsfederation.org or contact the secretariat office at (403) 229-9544.

June 10-13, 2009

Daegu, Korea

10th Asian & Oceanian Congress of Child Neurology

For registration, hotel information and other information go to www.aoccn2009.com.

July 7-10, 2009

Toronto, Ontario, Canada

SickKids Centre for Brain & Behaviour 1st Annual International Symposium

Visit www.sickkids.ca/learninginstitute or email li.conferences@sickkids.ca.

August 27-30, 2009

Munich, Germany

1st International Congress on Clinical Neuroepidemiology

For information about our Congress, please go to our website:
www.neuro2009.com.

August 30-September 4, 2009

Boston, Massachusetts, USA

XIV Congress of the World Federation of Neurosurgical Societies (WFNS)

For more information or to register, please visit
www.AANS.org/wfns2009 or email wfns2009@aans.org



PRESCRIBING SUMMARY

PATIENT SELECTION CRITERIA

THERAPEUTIC CLASSIFICATION: Analgesic Agent

INDICATIONS AND CLINICAL USE

LYRICA is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy and postherpetic neuralgia in adult patients. LYRICA may be useful in the management of central neuropathic pain in adult patients for which it has been issued marketing authorization with conditions to reflect the promising nature of the clinical evidence and the need for a confirmatory study to verify its clinical benefit. Patients should be advised of the nature of the authorization.

CONTRAINDICATIONS: Patients who are hypersensitive to pregabalin or to any ingredient in the formulation or component of the container.

SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Tumorigenic Potential: In standard preclinical in vivo lifetime carcinogenicity studies of pregabalin, a high incidence of hemangiosarcoma was identified in two different strains of mice. The clinical significance of this finding is uncertain. Clinical experience during pregabalin's premarketing development provides no direct means to assess its potential for inducing tumors in humans.

Ophthalmological Effects: In controlled studies, pregabalin treatment was associated with vision-related adverse events such as blurred vision (amblyopia) (6% pregabalin and 2% placebo) and diplopia (2% pregabalin and 0.5% placebo). Approximately 1% of pregabalin-treated patients discontinued treatment due to vision-related adverse events (primarily blurred vision). Of the patients who did not withdraw, the blurred vision resolved with continued dosing in approximately half of the cases (see Product Monograph, **Post-Marketing Adverse Drug Reactions**).

Patients should be informed that if changes in vision occur, they should notify their physician.

Peripheral Edema: In controlled clinical trials pregabalin treatment caused peripheral edema in 6% of patients (336/5508) compared with 2% of patients (42/2,384) in the placebo group. In these studies, 0.5% (28/5508) of pregabalin patients and 0.2% (4/2,384) of placebo patients withdrew due to peripheral edema (see Product Monograph, **ADVERSE REACTIONS, Peripheral Edema**).

In controlled clinical trials of up to 13 weeks in duration of patients without clinically significant heart or peripheral vascular disease, there was no apparent association between peripheral edema and cardiovascular complications such as hypertension or congestive heart failure. In the same trials, peripheral edema was not associated with laboratory changes suggestive of deterioration in renal or hepatic function.

Higher frequencies of weight gain and peripheral edema were observed in patients taking both LYRICA (pregabalin) and a thiazolidinedione antidiabetic agent compared to patients taking either drug alone.

As the thiazolidinedione class of antidiabetic drugs can cause weight gain and/or fluid retention, possibly exacerbating or leading to heart failure, care should be taken when co-administering LYRICA and these agents.

Congestive Heart Failure: In controlled clinical studies, events of congestive heart failure were reported at an infrequent rate (between 0.1% and 1%; see Product Monograph, **ADVERSE REACTIONS, Less Common Clinical Trial Adverse Reactions**).

There have been post-marketing reports of congestive heart failure in some patients receiving pregabalin (see Product Monograph, **ADVERSE REACTIONS, Post-marketing Adverse Drug Reactions**). These reactions are mostly seen in elderly cardiovascular compromised patients during pregabalin treatment for

a neuropathic pain indication. Pregabalin should be used with caution in these patients. Discontinuation of pregabalin may resolve the reaction.

Weight Gain: Pregabalin treatment was associated with weight gain. In pregabalin controlled clinical trials of up to 13 weeks, a gain of 7% or more over baseline weight was observed in 8% of pregabalin treated patients and 2% of placebo-treated patients. Few patients treated with pregabalin (0.2%) withdrew from controlled trials due to weight gain (see Product Monograph, **ADVERSE REACTIONS, Weight Gain**). Pregabalin-associated weight gain was related to dose and duration of exposure, but did not appear to be associated with baseline BMI, gender, or age. Weight gain was not limited to patients with edema (see Product Monograph, **WARNINGS AND PRECAUTIONS, Peripheral Edema**).

Although weight gain was not associated with clinically important changes in blood pressure in short-term controlled studies, the long-term cardiovascular effects of pregabalin-associated weight gain are unknown.

While the effects of pregabalin-associated weight gain on glycemic control have not been systematically assessed, in controlled and longer-term open label clinical trials with diabetic patients, pregabalin treatment did not appear to be associated with loss of glycemic control (as measured by HbA_{1c}).

Dizziness and Somnolence: In controlled neuropathic pain studies, pregabalin caused dizziness in 23% of patients (424/1,831) compared to 7% in placebo (58/857). Somnolence was experienced by 14% (256/1,831) and 4% (33/857) of the patients treated with pregabalin and placebo, respectively. These events begin shortly after the initiation of therapy and generally occur more frequently at higher doses.

Abrupt or Rapid Discontinuation: Following abrupt or rapid discontinuation of pregabalin, some patients reported symptoms including insomnia, nausea, headache, and diarrhea. Pregabalin should be tapered gradually over a minimum of one week rather than discontinued abruptly (see Product Monograph, **ADVERSE REACTIONS, Adverse Events Following Abrupt or Rapid Discontinuation**).

ADVERSE REACTIONS

Clinical Trial Adverse Drug Reactions: *Most Common Adverse Events in All Pre-marketing Controlled Clinical Studies of Peripheral Neuropathic Pain:* The most commonly observed adverse events ($\geq 5\%$ and twice the rate of that seen in placebo) in pregabalin-treated patients were: dizziness, somnolence, peripheral edema, and dry mouth. Adverse events were usually mild to moderate in intensity.

Adverse Events From a Controlled Clinical Study in Central Neuropathic Pain Associated With Spinal Cord Injury: The most commonly observed treatment-related adverse events ($\geq 5\%$ and twice the rate of that seen in placebo) in pregabalin-treated patients were: somnolence, dizziness, asthenia, dry mouth, edema, myasthenia, constipation, thinking abnormal, amblyopia, and amnesia. Adverse events were usually mild to moderate in intensity.

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by telephone: 1-866-234-2345.

ADMINISTRATION

Dosing Considerations

Patients with Impaired Renal Function: Pregabalin is primarily eliminated from the systemic circulation by renal excretion as unchanged drug. In patients with a medical history of significant renal insufficiency, daily dosages should be reduced accordingly (see Table in Supplemental Product Information).

Adults:

Neuropathic pain associated with diabetic peripheral neuropathy and postherpetic neuralgia: The recommended starting dose for LYRICA is 150 mg/day, given in two or three divided doses (75 mg BID or 50 mg TID), with or without food in patients with a creatinine clearance rate of at least 60 mL/min. Efficacy of LYRICA has been demonstrated within the first week. Based on individual patient response and tolerability, the dose may be increased to 150 mg BID (300 mg/day) after one week.

For patients who experience significant and ongoing pain and can tolerate pregabalin 300 mg/day well, maximum daily dose of 600 mg (300 mg BID) can be used. However, in clinical trials, LYRICA 600 mg/day did not provide additional significant efficacy and patients treated with this dose experienced markedly higher rates of adverse events and discontinued the trial more frequently.

Central neuropathic pain: The recommended starting dose for LYRICA is 150 mg/day, given in two divided doses (75 mg BID), with or without food in patients with a creatinine clearance rate of at least 60 mL/min. Efficacy of LYRICA has been demonstrated within the first week. Based on individual patient response and

tolerability, the dose may be increased to 150 mg BID (300 mg/day) after one week. For patients who experience significant and ongoing pain and can tolerate pregabalin 300 mg/day well, a maximum daily dose of 600 mg (300 mg twice a day, BID) may be considered.

Administration: LYRICA is given orally with or without food.

Supplemental Product Information

Special Populations: Geriatrics (≥65 years of age): Pregabalin oral clearance tended to decrease with increasing age. This decrease in pregabalin oral clearance is consistent with age-related decreases in creatinine clearance. Reduction of pregabalin dose may be required in patients who have age-related compromised renal function (see Product Monograph, **WARNINGS AND PRECAUTIONS, Geriatrics >65 years of age**).

Pregnant Women: There are no adequate and well-controlled studies in pregnant women. Pregabalin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Labour and Delivery: The effects of pregabalin on labour and delivery in pregnant women are unknown.

Nursing Women: It is not known if pregabalin is excreted in human breast milk; however, it is present in the milk of rats. Because of the potential for adverse reactions in nursing infants from pregabalin, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatrics (<18 years of age): The safety and efficacy of pregabalin in pediatric patients (<18 years of age) have not been established and its use in this patient population is not recommended (see Product Monograph, **WARNINGS AND PRECAUTIONS, Pediatrics**).

WARNINGS AND PRECAUTIONS: See the Product Monograph for further information on the following: tumorigenic potential, ophthalmological effects, peripheral edema, congestive heart failure, weight gain, dizziness and somnolence, sexual function/reproduction, and special populations.

DRUG INTERACTIONS

Overview: Since pregabalin is predominately excreted unchanged in the urine, undergoes negligible metabolism in humans (<2% of a dose recovered in urine as metabolites), does not inhibit drug metabolism in vitro, and is not bound to plasma proteins, LYRICA (pregabalin) is unlikely to produce, or be subject to, pharmacokinetic interactions.

Drug Abuse and Dependence/Liability: Pregabalin is not known to be active at receptor sites associated with drugs of abuse. As with any CNS active drug, physicians should carefully evaluate patients for history of drug abuse and observe them for signs of LYRICA misuse or abuse (e.g., development of tolerance, dose escalation, drug-seeking behaviour).

ADMINISTRATION

Dosage Adjustment Based on Renal Function: Dosing adjustment should be based on creatinine clearance (CL_r), as indicated in Table 1.

Pregabalin is effectively removed from plasma by hemodialysis. Over a 4-hour hemodialysis treatment, plasma pregabalin concentrations are reduced by approximately 50%. For patients receiving hemodialysis, pregabalin daily dose should be adjusted based on renal function. In addition to the daily dose adjustment, a supplemental dose should be given immediately following every 4-hour hemodialysis treatment (see Table below).

Table 1. Pregabalin Dosage Adjustment Based on Renal Function

Creatinine Clearance (CL _r) (mL/min)	Total Pregabalin Daily Dose (mg/day) ^a Recommended Dose Escalation ^a			Dose Regimen
	Starting dose		Maximum daily dose	
≥60	150	300	600	BID or TID
30-60	75	150	300	BID or TID
15-30	25-50	75	150	QD or BID
<15	25	25-50	75	QD
Supplementary dosage following hemodialysis (mg) ^b				
Patients on the 25 mg QD regimen: take one supplemental dose of 25 mg or 50 mg				
Patients on the 25-50 mg QD regimen: take one supplemental dose of 50 mg or 75 mg				
Patients on the 75 mg QD regimen: take one supplemental dose of 100 mg or 150 mg				

TID = Three divided doses; BID = Two divided doses; QD = Single daily dose.

^a Based on individual patient response and tolerability.

^a Total daily dose (mg/day) should be divided as indicated by dose regimen to provide mg/dose.

^b Supplementary dose is a single additional dose.

OVERDOSAGE

Signs, Symptoms and Laboratory Findings of Acute Overdosage in Humans: The highest known dose of pregabalin received in the clinical development program was 15,000 mg in 1 patient. The types of adverse events experienced by patients who received an overdose were not clinically different from other patients receiving recommended doses of pregabalin.

Treatment or Management of Overdose: There is no specific antidote for overdose with pregabalin. If indicated, elimination of unabsorbed drug may be attempted by emesis or gastric lavage; usual precautions should be observed to maintain the airway. General supportive care of the patient is indicated including monitoring of vital signs and observation of the clinical status of the patient. A Certified Poison Control Center should be contacted for up-to-date information on the management of overdose with pregabalin.

Hemodialysis: Standard hemodialysis procedures result in significant clearance of pregabalin (approximately 50% in 4 hours) and should be considered in cases of overdose. Although hemodialysis has not been performed in the few known cases of overdose, it may be indicated by the patient's clinical state or in patients with significant renal impairment.

AVAILABILITY OF DOSAGE FORMS

LYRICA is available in dosage strengths of 25 mg, 50 mg, 75 mg, 100 mg,* 150 mg, 200 mg,* 225 mg,* and 300 mg capsules.

* Not commercially available in Canada

For a copy of the Product Monograph or full Prescribing Information, please contact: Pfizer Canada Medical Information at 1-800-463-6001 or visit www.pfizer.ca.



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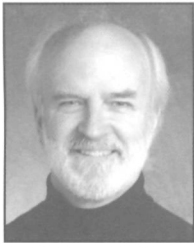
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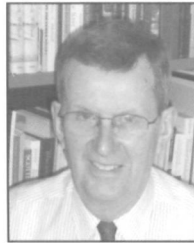
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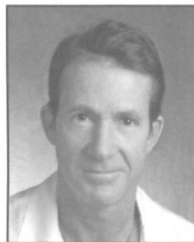
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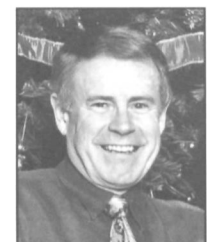
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Legend:

CNSF - Canadian Neurological Sciences Federation; NSFC - Neurological Sciences Foundation of Canada; CNS - Canadian Neurological Society; CNSS - Canadian Neurosurgical Society; CSCN - Canadian Society of Clinical Neurophysiologists; CACN - Canadian Association of Child Neurology; CBANHC - Canadian Brain and Nerve Health Coalition

**Canadian Neurological Sciences Federation 44th Annual Congress
Preliminary Program (Tentative) – as at November 20th, 2008**

Tuesday, June 9/09

7:15 – 8:30	Residents' Breakfast
8:30 - 5:00	ALS
8:00 - 5:00	Advances in the Neurobiology of Disease <i>Chairs: Peter Dirks and Peter Smith</i>
8:30 - 5:00	Child Neurology Day <i>Chairs: Harvey Sarnat and Joe Dooley</i>
12:00 - 1:30	Lunch
6:00 - 8:00	Epilepsy Video Session <i>Chair: Richard McLachlan</i>
6:00 - 8:00	Movement Disorders SIG <i>Chair – Alex Rajput</i>
6:00 - 8:00	Headache SIG <i>Chair TBC – Marek Gawel/Werner Becker</i>
6:00 - 8:00	Neuromuscular SIG <i>Chair – Kristine Chapman</i>

Wednesday, June 10/09

8:00 - 10:00	Grand Opening Plenary-Scientific & Technical Advances in the Clinical Neurosciences: <i>Cornelius Tulleken / Mark Bernstein / Ivar Mendez</i>
10:00 - 10:15	Coffee Break
10:15 - 11:45	Chair's Select Plenary Presentations
12:00 - 1:30	Co-developed Industry Symposium
12:00 - 1:30	Co-developed Industry Symposium
1:30 - 5:00	Neuroradiology <i>Chair: Timo Krings</i>
1:30 - 5:00	Spine <i>Chair: Eric Massicotte</i>
1:30 - 5:00	Medical and Surgical Stroke Prevention <i>Chair: Max Findlay & Gord Gubitz</i>
1:30 - 5:00	Neurocritical Care <i>Chair: Jeanne Teitelbaum</i>
1:30 - 5:00	Epilepsy <i>Chairs: Francois Dubeau</i>
1:30 - 5:00	EMG <i>Chairs: Ian Grant and Timothy Benstead</i>
1:30 - 5:00	Neuro-ophthalmology <i>Chair: William Fletcher</i>
5:00 – 6:30	Opening of Exhibits Reception
6:30 – 8:00	Co-developed Industry Symposium
6:30 – 8:00	Co-developed Industry Symposium

Thursday, June 11/09

8:00 - 9:30	Plenary-CNS, CACN, & CSCN Neurology <i>Michael Sinnreich / Brenda Banwell</i>
8:00 - 9:30	Plenary-CNSS Neurosurgery <i>Michael West / Gary Steinberg</i>
9:30 -10:00	Coffee Break
10:00 - 12:15	Platforms (7 simultaneous)
12:15 - 2:00	Lunch/Exhibit Viewing/Digital Mini-platforms
2:00 - 4:30	Platforms (7 simultaneous)
4:30 - 5:30	Digital Poster and Exhibit Viewing
6:00 - 8:00	Presidents' Social

Friday, June 12/09

8:00 - 9:00	Distinguished guest lecture
9:00 - 9:15	Journal Editor's Report
9:15 - 9:30	CBANHC Report
9:30 - 10:15	Coffee break/Exhibit viewing
10:15 - 12:00	Grand Rounds
12:00 - 1:30	Lunch / Exhibit viewing / Digital Mini-platforms
1:30 - 5:00	Peripheral Nerve <i>Chair: Raj Midha</i>
1:30 - 5:00	What's New in Neurosurgery? <i>Chair: Ian Fleetwood</i>
1:30 - 5:00	EEG <i>Chair: Seyed Mirsattari</i>
1:30 - 5:00	Endoscopy <i>Chair: Mark Hamilton</i>
1:30 - 5:00	Dementia <i>Chair: Sultan Darvesh</i>
1:30 - 5:00	What's New in Neurology? <i>Chair: Roger McKelvey</i>
1:30 - 5:00	MS <i>Chair: Virender Bhan</i>

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NEW

Pregabalin: First and only first-line analgesic with a conditional indication in central neuropathic pain

LYRICA may be useful in the management of central neuropathic pain (NeP) in adult patients for which it has been issued marketing authorization with conditions to reflect the promising nature of the clinical evidence and the need for a confirmatory study to verify its clinical benefit. Patients should be advised of the nature of the authorization.

LYRICA®

Powerful Pain Relief

Powerful. Fast onset. Sustained relief.

- Pain relief shown in postherpetic neuralgia (PHN) and central NeP as early as week 1 and demonstrated over 3 months^{1,3-4}
- Improvement shown in pain-related sleep interference in PHN and central NeP as early as week 1 and demonstrated over 3 months¹⁻⁴

Significant improvement in overall status.

- Significant improvement demonstrated in patient-reported overall status (Patient Global Impression of Change [PGIC]) in patients with peripheral NeP [diabetic peripheral neuropathy (DPN) or PHN] and central NeP^{1-3,5-11}

LYRICA (pregabalin) is an analgesic indicated for the management of neuropathic pain (NeP) associated with DPN and PHN.

LYRICA is contraindicated in patients who are hypersensitive to pregabalin or to any ingredient in the formulation or component of the container. The most commonly observed adverse events ($\geq 5\%$ and twice the rate as seen with placebo) were dose related for PHN and DPN patients in the recommended dose range of 150 mg/day to 600 mg/day; dizziness (9.0-37.0%), somnolence (6.1-24.7%), peripheral edema (6.1-16.2%), and dry mouth (1.9-14.9%). The most commonly observed adverse events seen in central NeP patients ($\geq 5\%$ and twice the rate as that seen with placebo) in the recommended dose range of 150 mg/day to 600 mg/day were: somnolence (41.4%), dizziness (24.3%), asthenia (15.7%), dry mouth (15.7%), edema (12.9%), constipation (12.9%), amnesia (10.0%), myasthenia (8.6%), amblyopia (8.6%), and thinking abnormal (8.6%). The most commonly observed adverse events in the PHN, DPN, and central NeP patients were usually mild to moderate in intensity. Discontinuation rates due to adverse events for LYRICA and placebo, respectively, were 9% and 4% in DPN, 14% and 7% in PHN and 21% and 13% in central NeP.

Dosage reduction is required in patients with renal impairment (creatinine clearance < 60 mL/min) as LYRICA is primarily eliminated by renal excretion.

Please see Prescribing Information for complete Warnings and Precautions, Adverse Reactions, Dosage and Administration and patient selection criteria.

¹ A 13-week, multicentre, double-blind, placebo-controlled trial in 389 patients with PHN. A significant difference in pain reduction was shown over placebo for all doses: 150 mg/day, 300 mg/day, and 600 mg/day ($p < 0.01$, weeks 1-13). Sleep interference was improved at all time points (weeks 1, 7, 13 and endpoint) for the three doses evaluated ($p < 0.01$ vs. placebo). PGIC was reported as improved in 35.5% of patients in the placebo group. At study termination, patients in the 150 mg/day ($p = 0.02$) and 600 mg/day group ($p = 0.003$) were more likely to report global improvement than those in the placebo group.

² Data based on a 12-week, parallel-group, double-blind, flexible-dose, placebo-controlled study. 137 patients with spinal cord injury for ≥ 1 year and who had a pain score ≥ 40 mm on the 100-mm visual analog scale (VAS) of the Short-Form-McGill Pain Questionnaire were randomized to LYRICA (150 mg/day, 300 mg/day, 600 mg/day) or placebo for the last seven days. Pain-related sleep interference scores rated on 11-point numerical scale from 0 (did not interfere) to 10 (completely interfered) during the past 24 hours averaged over the last seven days. A significant difference in pain reduction was demonstrated for the LYRICA group vs. placebo at all time points evaluated ($p < 0.01$, weeks 1-7 and endpoint) and PGIC was improved at all time points for LYRICA group ($p < 0.01$, weeks 1-7 and endpoint). At study termination, patients in the LYRICA and placebo treatment groups were reported as (at least minimally) improved by 56.5% and 21.5% of patients in the LYRICA and placebo groups, respectively ($p < 0.001$ for overall LYRICA comparison vs. placebo across "improved", "unchanged" and "worse" subgroups).

weeks 4-12), and the fixed dose of 600 mg/day ($p < 0.05$, week 1 and $p < 0.01$, weeks 2-12). PGIC was reported as very much improved or much improved by 32.0% of the flexible-dose group, 53.6% of the fixed-dose group and 33.3% of the placebo group ($p < 0.01$ for overall comparison).
³ Data on file. Pfizer Canada Inc., 2333 Avenue McGillivray, Scarborough, Ontario M1V 5A4, Canada.
⁴ IP et al. Efficacy and tolerability of twice-daily pregabalin for treating pain and related sleep interference in postherpetic neuralgia: a 13-week randomized trial. *Curr Med Res Opin* 2006; 22(2):375-84.
⁵ Siddall PJ et al. Pregabalin in central neuropathic pain associated with spinal cord injury: a placebo-controlled trial. *Neurology* 2006; 67:1792-800.
⁶ LYRICA Product Monograph, Pfizer Canada Inc., 2006.
⁷ Lyrica (pregabalin) Tablets, 150 mg, 300 mg, 600 mg, immediate-release tablets, multi-centre, placebo-controlled trial of flexible and fixed-dose regimens. *Pain* 2006; 115:254-63.



Fast onset. Sustained relief.
See prescribing summary A-9, A-10